Validation of the Hingmed WBP-02A upper arm oscillometric monitor for ambulatory blood pressure measurement in a general population, according to the European Society of Hypertension International Protocol revision 2010

Claudio Fania,MD, Leonardo Vezzù,RN, Ilaria Lazzaretto,RN, Paolo Palatini, MD

Keywords: Validation, device, oscillometric, blood pressure, ambulatory.

For Claudio Fania, Leonardo Vezzù, and Ilaria Lazzaretto:
Casa di Cura Villa Maria, via delle Melette, 20, 35138 Padova, Italy

For Paolo Palatini:
via San Fris, 121, 31029 Vittorio Veneto, Italy

Correspondence to Doctor Claudio Fania, Casa di Cura Villa Maria, via delle Melette, 20, 35138 Padova,
Tel: 049 8711144; e-mail: fania.claudio@gmail.com

Abstract

The Hingmed WBP-02A, an upper arm oscillometric monitor, for ambulatory BP measurement was validated in a general population, according to the European Society of Hypertension International Protocol revision 2010. The protocol requirements were followed precisely. The device passed all of the requirements fulfilling the standards of the protocol. Thus, the WBP-02A device is recommended for clinical use in the adult general population.

Device Details

Brand	Hingmed
Model	WBP-02A
Manufacturer	Shenzhen Hingmed Medical Instrument Co., Ltd
Location	Upper Arm
Method	Oscillometry
Purpose	ABPM
Operation	Fully Automatic
Arm Cuffs	Small Adult: 18.0 cm to 26.0 cm, Standard Adult: 22.0 cm to 32.0 cm, Large Adult: 26.0 cm to 36.0 cm and other cuffs: 30.0 cm to 43.0 cm

Methodology

Familiarisation

Forty test measurements were carried out. No problems were encountered.

Recruitment

The WBP-02A device was evaluated in 37 adult individuals with BPs in the ranges required by the protocol. The participants were recruited from the outpatient clinics, wards, and from among the healthcare personnel of the Hospital Villa Maria, Padua, Italy. Four participants were excluded because their BP was within the BP ranges already completed, leaving an overall number of 33 participants. There was some difficulty in recruiting patients with BP in the high ranges, but apart from this there was no problem.

Screening and Recruitment Details

Screening and Recruitment		Recruitment Ranges				
Total Screened	37			mmHg	All	On Rx
Total Excluded	4		Low	< 90	0	3
Ranges Complete	0			90 - 129	11	
Ranges Adjustment	0	SBP	Medium	130 - 160	12	6
Arrhythmias	0		High	161 - 180	10	4
Device Failure	0			> 180	0	
Poor Quality Sounds	0					
Cuff Size Unavailable	0		Low	< 40	0	3
Observer Disagreement	0			40 - 79	11	
Distribution	0	DBP	Medium	80 - 100	12	6
Other Reasons	4		High	101 - 130	10	4
Total Recruited	33			> 130	0	

Procedure

The European Society of Hypertension International Protocol revision 2010 for the validation of blood pressure measuring devices in adults was followed precisely.[1] Overseen by an independent supervisor, measurements were recorded by two observers blinded from both each other's readings and from the device readings. No technical problem was encountered during the validation study.

Results

Subject Details

Sex		
Male : Female	14 : 19	
Age (years)		
Range (Low : High)	32 : 91	
Mean (SD)	69.8 (13.8)	
Arm Circumference (cm)		
Range (Low : High)	20.0 : 43.0	
Mean (SD)	30.1 (6.2)	
Cuff for test device		
Small	6	(18.0 - 26.0 cm)
Standard	15	(22.0 - 32.0 cm)
Large	6	(26.0 - 36.0 cm)
Other	6	(30.0 - 43.0 cm)
	SBP	DBP
Recruitment BP (mmHg)		
Range (Low : High)	96 : 172	48 : 124
Mean (SD)	137.6 (27.0)	86.7 (20.1)

Observer Measurements in each Recruitment Range

SBP (mmHg)		DBP (mmHg)	
Overall Range (Low : High)	91 : 172	Overall Range (Low : High)	45 : 121
Low (< 130)	36	Low (< 80)	34
Medium (130 – 160)	39	Medium (80 – 100)	39
High (> 160)	24	High (> 100)	26
Maximum Difference	15	Maximum Difference	13

Observer Differences

	SBP (mmHg)	DBP (mmHg)	Repeated measurements
Observer 2 – Observer 1			
Range (Low : High)	-4 : +4	-4 : +4	
Mean (SD)	1.6 (1.7)	1.2 (1.7)	0

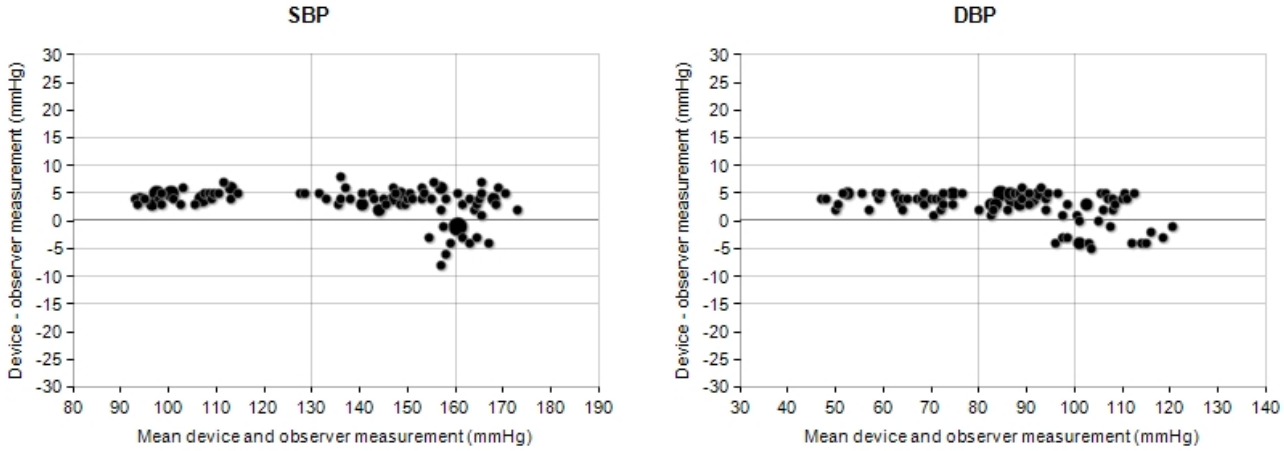
Validation Results

Part 1		≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg	Grade 1	Mean (mmHg)	SD (mmHg)
	Pass Requirements						
	Two of	73	87	96			
	All of	65	81	93			
	Achieved						
	SBP	84	99	99	Pass	3.3	2.9
	DBP	97	99	99	Pass	2.7	2.8

Part 2		2/3 ≤ 5 mmHg	0/3 ≤ 5 mmHg	Grade 2	Grade 3
	Pass Requirements	≥ 24	≤ 3		
	Achieved				
	SBP	32	0	Pass	Pass
	DBP	33	0	Pass	Pass

Part 3	Result
	PASS

Plots



Discussion

The present study demonstrated that the WBP-02A BP monitor met the ESH-IP standards for use in the general adult population because it passed all phases of the 2010 ESH revision Protocol. The recruitment of individuals in the high BP range proved to be difficult and accounted for the extra number of screened participants. Visual inspection of the device–observer discrepancies showed that the error was unrelated to patient BP levels and that the discrepancies were not higher at the extremes of BP.

As the WBP-02A device has reached the required ESH-IP standards, it can be recommended for ambulatory BP monitoring in the general population.

Conclusion

As the device has reached the required standards, it is recommended for clinical and personal use in a general population.

Acknowledgements and Conflict of Interest

The manufacturer supplied three test devices and confirmed that they had been selected from a normal production line. One device was then randomly selected for the validation study. The study was funded by a grant provided by Hingmed, China.

References

1. O'Brien E, Atkins N, Stergiou G, Karpettas N, Parati G, Asmar R, Imai Y, Wang J, Mengden T, Shennan A; on behalf of the Working Group on Blood Pressure Monitoring of the European Society of Hypertension. European Society of Hypertension International Protocol revision 2010 for the Validation of Blood Pressure Measuring Devices In Adults. Blood Press Monit 2010;15:23–38.